



Clash of the Titans: Conflicts in the Regulation of Medical Devices by the FDA and PTO

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Clash of the Titans:

Conflicts in the Regulation of Medical Devices by the FDA and PTO

by

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Abstract

This paper discusses two of the conflicts created by the fact that both the Food and Drug Administration and the Patent and Trademark Office regulate medical devices and drugs. A brief description of the two agencies is made to give a sense of their goals and of their resources involved. The conflicts discussed are the effect each agency has on the monopolistic power a company may have in the market, and the problem arising from the term “substantial equivalence” being used by the agencies for very contrary goals. With each conflict, the method to resolve the problem is discussed, be it by acts of Congress, the Courts, or the industry itself.

I. Introduction

From the outset of the forming of the United States, a system was put into place to encourage the development of new and useful inventions to aid its citizens. The goal was initially set by placing within the constitution itself the obligation that “to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.”¹ This exclusionary rights in the sciences comes in the form of a grant of a patent to whomever is the first invent something new. The power to regulate and grant such patents was eventually placed under the domain of the United States Patent and Trademark Office (PTO), making it an extremely important and powerful entity for any corporation to deal with. This patent scheme has been very successful leading to over 6.8 million inventions

¹U.S. Const. art. I, § 8, cl. 8.

patented to date.² The promotion of discovery and development is not, however, the only goal of Congress when it comes to new inventions. Among its many aims, Congress also seeks to protect the health and safety of all citizens. While tort law developed in the courts can act as a safety mechanism by creating incentives for companies to maintain a goal of safety through the concept of products liability, Congress has determined that there is a need to have a more paternal role in the distribution and use of certain products. For inventions falling in the category of drugs or medical devices, the regulation of their safety was delegated to the Food and Drug Administration (FDA), an agency whose track record has made it one of the most trusted (and therefore powerful) government agencies.

The collision of these two administrative agencies' regulations has lead to some unforeseen consequences. Some of these issues have been addressed through acts of Congress, while others have not been fully realized. While each of these collisions could theoretically have detrimental effects on those that produce drugs and medical devices, the industry as a whole has at least one advantage – sheer numbers. The medical industry alone employs over 280,760 people.³ As the discussion that follows will cover, this significantly outnumbers the employees in the federal government who are meant to oversee the regulation of both the granting of patents and the safety of the inventions. This paper will point out some of the effects the dual-bodied regulation scheme has on drugs and medical devices, as well as some of the legislation Congress has enacted to address the issue. While the main focus of this paper is on medical devices, as will be seen, it is impossible to discuss the issue without also discussing the different treatment drugs are given by the two agencies.

II. The Agencies Involved

²Patent number 6800000 was granted October 5, 2004.

³Benjamin A. Goldberger, The Evolution of Substantial Equivalence in FDA's Premarket Review of Medical Devices, 56 Food Drug L.J. 317, 317 (2001).

Before delving into the complexities created by the dual-bodied regulatory scheme, it is helpful to have an understanding of how each of the agencies involved is organized and how it became involved in the regulation of drugs and medical devices.

A. The USPTO

As previously stated, the first U.S. patent laws were enacted by Congress in 1790 as part of the U.S. Constitution. The very first patent granted in the United States was signed by George Washington on July 31, 1790 after being reviewed by Thomas Jefferson who acted as patent examiner.⁴ The patent was for a new method of making Potash, an industrial chemical used in making soap, glass, fertilizers and gunpowder, and was granted to Samuel Hopkins of Pittsford, Vermont.⁵ The ability to grant patents for medical devices has always been a part of the patent statutes that now regulate the granting of this exclusive control.⁶

The United States Patent and Trademark office was established by Congress to issue patents on behalf of the Federal Government.⁷ The origin of the Patent and Trademark Office as a separate and distinct bureau dates to 1802 when the position of the Superintendent of Patents was created within the Department of State to oversee all patents.⁸ Later, the official in charge of the Patent and Trademark Office was given the designation of Commissioner of Patents and Trademarks through revisions in the patent laws in 1836.⁹ The agency remained a part of the Department of the state for about forty seven years, when it was then

⁴Mary Bellis, The 212th Anniversary of the First American Patent Act, at (last visited March 10, 2005) <http://inventors.about.com/library/weekly/aa073100a.htm>.

⁵Id.

⁶35 U.S.C. § 101 (1952) (“Who invents or discovers any new and useful process, machine, manufacture, or composition of matter...”).

⁷THE UNITED STATES PATENT AND TRADEMARK OFFICE, at (last visited March 10, 2005) <http://www.uspto.gov/web/offices/pac/doc/general/uspto.htm>.

⁸Id.

⁹Id.

transferred to the Department of Interior in 1849.¹⁰ The Patent and Trademark Office's current location began in 1925 when it was transferred to the Department of Commerce.¹¹

Although all patent regulation is controlled by the PTO, it is important to note that there is a significant limit to that power. Once the Patent and Trademark Office grants a patent application, its jurisdiction ends and it has no control over the issued patent with only one minor exception.¹² Any issues involving the infringement of a patent or its enforcement can only be examined by a court; the agency has no authority to investigate. Likewise, the interests of the PTO in any patent do not cover matters relating to the promotion or use of the patents so long as their usefulness was proven during the application process.¹³

The current composition within the Patent and Trademark Office has half of its 5,700 employees as patent examiners with technical or legal training.¹⁴ It is estimated that over 200,000 applications are received for review by the examiners as part of the over five million pieces of mail received by the Patent and Trademark Office every year.¹⁵ The PTO has been fully fee funded since 1991, after Congress passed the Omnibus Budget Reconciliation Act (OBRA).¹⁶

B. The Food and Drug Administration

The FDA's origin can be traced back to 1862 where it was run as a division of the United States Department

¹⁰Id.

¹¹Id.

¹²If a clerical error was made in the issuance of a patent, the patent is once again before the PTO to be reissued with all the proper corrections. 35 U.S.C. § 251 (1999)

¹³35 U.S.C. § 101 (1952).

¹⁴United States Patent and Trademark Office, at (last visited March 10, 2005) http://law.freeadvice.com/resources/gov_material/patent_and_trademark_office_general_information_on_office.htm

¹⁵Id.

¹⁶Our Business: An Introduction to the USPTO, at (last visited March 10, 2005) <http://www.uspto.gov/web/menu/intro.html>

of Agriculture.¹⁷ Although its place among the executive branch has shifted over the years, its principle mission has remained the same - to ensure the safety and truthful labeling of all products under its domain.¹⁸ While the regulation of drugs was clearly within the FDA's power almost from the outset, medical device regulation is a more recent part of its history.

The Federal Food, Drug, and Cosmetic Act (FDCA) of 1938 was the first bill containing a provision clearly directed towards the regulation of medical devices by the FDA. Interestingly, this attention appears only to have occurred because the idea that “treating a mechanical device as a drug in law and in logic and in lexicography [was] a palpable absurdity to Senator Clark, Democrat from Missouri, and several other senators.”¹⁹ Although the semantics surrounding medical devices warranted a different definition within the act, the treatment of medical devices was intended to remain the same as that of drugs. Despite the intent to keep the two regulations identical, when Congress passed legislation requiring premarket approval of new drugs, what appears to be a simple oversight left medical devices without a similar regulatory change.²⁰ This was a significant problem because the premarket approval process was the best way to ensure that there were no dangerous products on the market, and has with time become one of the main enforcement mechanisms of the agency. The FDA was limited in its power over medical devices and restricted to challenging the sale of products that it believed were adulterated (unsanitary or unsafe) or misbranded (bearing false or misleading claims).²¹ The difference in treatment between drugs and medical devices was made even greater in 1962, when the possibility of increasing regulatory power over medical devices was set aside to pass drug legislation.²²

¹⁷PETER BARTON HUTT & RICHARD A. MERRILL, FOOD AND DRUG LAW: CASES AND MATERIALS, 4 (2d ed. 1991).

¹⁸Id. at 5.

¹⁹Goldberger, *supra* note 3, at 319 (internal quotations omitted).

²⁰Richard A. Merrill, The Architecture Of Government Regulation Of Medical Products, 82 Va. L. Rev. 1753, 1802 (1996).

²¹Id.

²²Id. at 1802-1803.

While regulation of medical devices remained far behind that of drugs, medical device technology continued to expand at an ever growing rate.²³ It became clear within the FDA that these new medical devices needed to be subject to a similar premarket review to that of drugs in order to assure the safety and effectiveness of the products.²⁴ The initial scheme devised to address the problem was to take advantage of the broad definition of a drug under the FDCA,²⁵ and to require clinical trials and premarket approval of diagnostic products and some other medical instruments.²⁶ While these attempts proved mildly successful, the overall application of this scheme was uncoordinated and resulted in unequal enforcement. As technology advanced, however, more and more medical devices fell out of the reach of the scheme.²⁷

An internal committee of the Department of Health, Education and Welfare was formed in 1970, and chaired by Heart Institute Director Theodore Cooper, to address the lack of control FDA had on medical devices and to create a blueprint for the system that should monitor the distribution of medical devices into the marketplace.²⁸ The key element to the commission's recommendation was the recognition that not all medical devices required the same level of regulation. Instead, a three tiered hierarchy was conceived so that the limited resources that could be devoted to the regulation of medical devices would be distributed in a way that would keep those devices that needed the most scrutiny under watch.²⁹ The difference in regulation between the three classes ranges from premarket approval for one set to simply policing misbranding of products of another set.

²³Id. at 1804.

²⁴Id.

²⁵Pub. L. No. 75-717, 52 Stat. 1040, § 201(g) (1938) (The term drug originally meant "(1) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary...and (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) articles (other than food) intended to affect the structure or any function of the body of man or other animals...but does not include devices....").

²⁶Merrill, *supra* note 20, at 1804.

²⁷Id.

²⁸Id. at 1806.

²⁹See Id.

The first category of devices, Class I medical devices, are those for which what are considered general controls are sufficient to provide a reasonable assurance of the safety and effectiveness of the devices.³⁰ These controls include registration with the FDA as a manufacturer,³¹ mechanisms to assure that device labeling is not false or misleading,³² and compliance with the current Good Manufacturing Practice regulations.³³ Some examples of Class I medical devices are elastic bandages,³⁴ tongue depressors,³⁵ and examination gloves.³⁶ A second set of devices, Class II medical devices, are those whose safety cannot be assured by the general controls governing Class I medical devices.³⁷ This class includes devices such as infusion pumps,³⁸ piston syringes,³⁹ and steam sterilizers.⁴⁰ To ensure the safety and effectiveness of these devices, an increased number of assurances are required by the FDA. Such measures include requiring performance standards, patient registries, and the development of guidelines.⁴¹

Those devices whose assurance of safety cannot be guaranteed by the general controls of Class I or through the special controls of Class II are categorized as Class III medical devices.⁴² In essence, the default classification of a device is within Class III unless it can be shown that the less stringent standards of the other two classes are sufficient. Typical devices that remain in this category are ones that support or sustain human life such as cardiac pacemakers⁴³ and implanted neuromuscular stimulators.⁴⁴ Allowing devices in this class onto the market typically requires a substantial amount of clinical trials to prove their safety and effectiveness.

³⁰30 U. Tol. L. Rev. 305, 312 (citing 21 U.S.C. § 360c(a)(1)(A) (1994)).

³¹Id.

³²Id. Citing § 352.

³³Id. Citing § 360j(f).

³⁴21 C.F.R. § 880.5075(b)

³⁵21 C.F.R. § 880.6230(b)

³⁶21 C.F.R. § 880.6250(b)

³⁷See 21 U.S.C. § 360c(a)(1)(B) (1994).

³⁸21 C.F.R. § 880.5725(b).

³⁹21 C.F.R. § 880.5860(b).

⁴⁰21 C.F.R. § 880.6880(b).

⁴¹See 21 U.S.C. § 360c(a)(1)(B) (1994).

⁴²See 21 U.S.C. § 360c(a)(1)(C) (1994).

⁴³See 21 C.F.R. § 870.3610(b) (1998).

⁴⁴See 21 C.F.R. § 882.5860(b).

The assurances of safety associated with Class I and II medical devices allows for a relatively simple process to introduce the devices into the market. Companies manufacturing these devices only need to complete a premarket notification process with the FDA to obtain clearance to commence marketing activities.⁴⁵ As part of the notification procedure, new medical devices need to have a substantial equivalence established to a device that has already been shown to meet the requirements of either Class I or II medical devices.⁴⁶ As will be discussed in the section to follow, the determination of what is required for substantial equivalence has changed over the years. At present, the term is defined within the FDCA, which if met, allows for approval to be based solely on appropriate scientific data rather than requiring clinical data.⁴⁷ Generally, a device is substantially equivalent to another device if it has the same intended use, and either the same technological characteristics⁴⁸ or different technological characteristics that do not raise different questions of safety and effectiveness.⁴⁹ The effect of this definition is that the premarket notification process boils down to a test comparing any new device to ones that have already been approved to enter into the market.⁵⁰ The premarket notifications have therefore evolved to focus on similarities new devices have to old ones,⁵¹ a process which brings with it consequences which will be discussed in the sections to follow.

⁴⁵J. Matthew Buchanan, Medical Device Patent Rights In The Age Of Fda Modernization: The Potential Effect Of Regulatory Streamlining On The Right To Exclude, 30 U. Tol. L. Rev. 305, 312 (1999); 21 U.S.C. § 360(k) (1996). The premarket notification process is commonly referred to as the 510(k) process. This label arises from the section of the FDCA which mandates it. See FDCA § 510(k); 21 U.S.C. § 360(k) (1996).

⁴⁶See 21 U.S.C. § 360c(i)(1)(A) (1994).

⁴⁷See *Id.*; Buchanan, *supra* note 45, at 313.

⁴⁸Buchanan, *supra* note 45, at 313 (“In a substantial equivalence determination, technological characteristics refer to items such as device design, materials and energy source. Food and Drug Law Inst., *supra* note 11, at 103-04.”).

⁴⁹*Id.*

⁵⁰Prior to the enactment of the Safe Medical Devices Act of 1990, Pub. L. No. 101-629, 104 Stat. 4511 (codified as amended at 21 U.S.C. enacting §§ 360 l and 383; amending §§ 321, 333, 351, 353, and 360c to 360j of this title and §§ 263b to 263n of Title 42, The Public Health & Welfare, redesignating §§ 263b to 263n of Title 42 as §§ 360gg to 360ss of this title; repealing § 263b of Title 42, and enacting provisions set out as notes under §§ 333, 360c, 360i, 360j, 360hh and 383 of this title (1994)), the predicate device had to be a device marketed prior to May 28, 1976. Food and Drug Law Inst., *supra* note 11, at 104. The predicate device cannot be a device that the FDA has removed from the market or one that a court has determined to be adulterated or misbranded. See 21 U.S.C. § 360c(i)(2).

⁵¹Buchanan, *supra* note 44, at 313.

III. The First Collision: Premarket Approval

As discussed above, one of the main enforcement mechanisms of the FDA is to require premarket approval for a product to be determined safe. The problem with such a system, however, is that it naturally increases the amount of time between when an invention is conceived and when it is placed in the hands of consumers. Normally, such a delay would probably be acceptable because the increased safety to the public outweighs the delay a company suffers before being able to recoup the cost of research. When a patent is involved, however, the cost to the company is significantly increased.

Although a patent grants a right of exclusivity to its owner, that exclusivity is only conferred for a limited amount of time. Previously the exclusivity of a patent lasted for seventeen years.⁵² More recently, the amount of time has been increased to twenty years.⁵³ This in turn means that a company can stop its competitors from taking advantage of the time and money it spent on research for only a limited amount of time. The problem is further compounded by the fact that the patent system is structured to force inventors to obtain a patent as soon as possible by removing the right to do so if it is not sought within a certain time limit.⁵⁴ A company could not, therefore, indefinitely postpone seeking a patent while trying to get premarket approval.

A. The solution to help inventors

⁵²See 35 U.S.C. § 154 (1952).

⁵³Pub.L. 103-465, Title V, § 532(a)(1), 108 Stat. 4983.

⁵⁴See 35 U.S.C. § 102 (2002).

To remove the penalty associated with the need for premarket approval for companies, Congress passed a patent term extension statute as part of the Orphan Drug Act.⁵⁵ The extension allows for at most an extension of five years to the patent to compensate for the delay that the premarket approval process produces.⁵⁶ Interestingly, this power to extend the patent term does not lie with anyone within the USPTO, but rather with the Secretary of Health and Human Services, or the FDA as Secretary's delegate.⁵⁷ While it makes sense the control of the extension rest with the organization most likely to know how long such an extension would require, it does further entangle the governance of the two agencies.

B. The solution to help the market

In addition to the problem that premarket approval creates for the inventor, it also had the capability of decreasing the amount of market competition available once a patent term expired. Although there are exceptions allowing someone without patent rights to use the subject of the patent, these exceptions did not cover the process of gaining premarket approval.⁵⁸ Generic product companies would potentially then be forced to not only wait for the patent term to expire to begin understanding how to develop the product, but then further wait until approval came from the FDA.⁵⁹ This of course is an undesirable effect, since it would essentially increase the patent term of the original inventor beyond what congress had intended.

⁵⁵See 35 U.S.C. § 155 (2002).

⁵⁶See 35 U.S.C. § 156 (2002).

⁵⁷See *Astra v. Lehman*, 71 F.3d 1578, 37 U.S.P.Q.2d 1212 (C.A.Fed., 1995)

⁵⁸See *Roche Prod., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984) (refused to apply the experimental use doctrine to activities conducted to generate data for submission to the FDA because such activities are not conducted for pure philosophical inquiry, but rather for commercial purposes).

⁵⁹See also *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 670 (1990) (observing that potential competitors of a patent holder could not initiate the development of information necessary for regulatory approval until after the patent had expired).

As a way to correct the unintended consequence of the dual-bodied governance, Congress tried to minimize the delay for competitors wishing to enter the market and decrease costs to consumers by passing the Drug Price Competition and Patent Term Restoration Act in 1984.⁶⁰ This part of the legislation modified the concept in that “It [would] not be an act of infringement to make use, offer to sell, or sell within the United States... a patented invention... solely for uses reasonably related to the development and submission of information under a federal law which regulates the manufacture, use, or sale of drugs.”⁶¹ This exception to infringement allowed manufactures of generic versions of drugs to begin the process of conducting the tests necessary to eventually gain FDA approval for their products.

Following Congress’ creation of the exemption, courts began to find a broad range of activities that met the criteria necessary to have the exemption apply.⁶² The activities now covered include the shipping of allegedly infringing drugs to a foreign distributor for purposes of conducting clinical trials,⁶³ the production of an allegedly infringing drug at commercial quantities,⁶⁴ the communication to potential customers of anticipated approval from the FDA,⁶⁵ the sales to clinical investigators of an allegedly infringing device,⁶⁶ the use of experimental data obtained during FDA required trials for non-FDA reporting purposes,⁶⁷ and using data to provide potential investors with information about an allegedly infringing product.⁶⁸ Eventually, the reasonably related requirement had been interpreted to allow for otherwise infringing activities without

⁶⁰Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984). See generally Ellen J. Flannery & Peter Barton Hutt, *Balancing Competition and Patent Protection in the Drug Industry: The Drug Price Competition Act of 1984*, 40 Food Drug Cosm. L.J. 269 (1985).

⁶¹Pub. L. No. 98-417, 98 Stat. 1585, § 202 (codified as amended at 35 U.S.C. § 271(e)(1)).

⁶²Buchanan, *supra* note 44, at 318.

⁶³See generally *NeoRx Corp. v. Immunomedics, Inc.*, 877 F. Supp. 202 (D.N.J. 1994).

⁶⁴*Id.*

⁶⁵*Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1030 (Fed. Cir. 1997).

⁶⁶*Intermedics, Inc. v. Ventritex, Inc.* 775 F.Supp. 1258, 1282-83 (N.D.Cal., 1991).

⁶⁷*Telectronics Pacing Systems, Inc. v. Ventritex, Inc.*, 982 F.2d 1520 (Fed. Cir. 1992).

⁶⁸*Intermedics*, 775 F. Supp. at 1281, 1284.

any actual submission to the FDA of the information obtained.⁶⁹

In addition to the broad construction given to the reasonable related requirement,⁷⁰ the Supreme Court has made the exception even greater in application. In *Eli Lilly & Co. v. Medtronic, Inc.*,⁷¹ the Supreme Court interpreted the exception as broad enough to encompass medical devices,⁷² even though it was originally considered applicable only to drug products.⁷³ That decision led the way for the more recent ruling by the Court of Appeals for the Federal Circuit in *Abtox v. Exitron*⁷⁴ explicitly allowing the section 271(e)(1) infringement exception to apply to all classes of medical devices.⁷⁵ Consequently, the exception now protects a wide array of activities and applies to all medical devices ranging from simple devices such as bandages to complex medical devices like cardiac pacemakers.⁷⁶ Following the rationales of the Lilly and Abtox decisions, it is arguable that the section 271(e)(1) exception today stands as a safe harbor for infringement for all products regulated by the FDA under the federal FDCA.⁷⁷

Congress' attempt to reconcile the two regulatory schemes' effect on the exclusive rights of inventors, while necessary, seems not to have been sufficient to fully solve the problem. The expansion of the section 271(e)(1)

⁶⁹See *Abtox*, 122 F.3d at 1027. While the activities at issue in *Abtox* were reasonably related to the development and submission of information to the FDA, the alleged infringer never actually filed an application for approval with the FDA.

⁷⁰Brian D. Coggio & Francis D. Cerrito, *The Application of the Patent Laws to the Drug Approval Process*, 52 *Food & Drug L.J.* 345, 346 (1997).

⁷¹496 U.S. 661 (1990).

⁷²*Lilly*, 496 U.S. at 678-79.

⁷³See *Flannery & Hutt*, *supra* note 28, at 308 ([The infringement exception] is limited to human drug products, and does not include medical devices, animal drugs, food additives, color additives, or other related products.). B at 23

⁷⁴*Abtox*, 122 F.3d 1019.

⁷⁵*Id.* at 1029.

⁷⁶*Sashank Upadhye, Understanding Patent Infringement Under 35 U.S.C. § 271(e): The Collisions Between Patent, Medical Device, And Drug Laws*, 17 *Santa Clara Computer & High Tech. L.J.* 1, 23 (2000) (citing *Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1030 (Fed. Cir. 1997).).

⁷⁷*Id.*

exception by the courts, while helpful to those in the medical device industry who wish to build off of the work of others, is far beyond what the legislature probably intended. It is hard to see how far down the chain of infringement a defendant may go in order to get FDA approval of the device in question.⁷⁸ One concern raised is that the current interpretation of section 271(e)(1) may not only allow infringement of a patent that is the sole subject of the intended FDA application, but may even cover more expansive patents.⁷⁹ Another issue is whether a potential infringement of several unrelated patents is permissible if the infringement of each patent is somehow reasonably related to gaining FDA approval of a device in question.⁸⁰ Additional amendments seem necessary for Congress to clarify where the proper balance between the FDA's and PTO's control of the monopoly aspect of patents should lie.

VI. The Second Collision: Substantial Equivalence

As discussed above, the use of premarket approval did not extend to medical devices until the late 1970s. By then, however, there were already a substantial amount of medical devices on the market.⁸¹ For the case of Class I and Class II devices, this new scheme was not a problem because the regulation involved could be applied equally to both pre and post 1976 Amendment devices.⁸² For Class III medical devices, a potentially big problem existed between those devices already on the market, and those that would have to be subject to the premarket approval process. If only post enactment devices would be subject to the

⁷⁸See *id.*

⁷⁹*Id.*

⁸⁰*Id.*

⁸¹See Goldberger, *supra* note 3, at 321-323.

⁸²*Id.*

new standards, then the government would be assisting companies already in the market in holding on to monopolies whether they actually held a patent on their device or not. While one theoretical solution could have been to take all preamendment devices off the shelves, this would obviously leave the public far worse off than before. The fact that the devices were accessible for a while meant that they were already subject to some amount of FDA scrutiny, and therefore to some degree were safe and therefore could and probably should remain accessible while new and improved devices were created.

The fact remained, however, that “the new requirements for proof of safety and efficacy would apply in discriminatory fashion [to Class III devices] if the statute were not written to avoid it.”⁸³ As a compromise to the problem, the draftsmen of the 1976 amendment included a provision linking the fate of postenactment Class III devices to their preenactment counterparts. Sections 513(f)(1)(A) and 515(b)(1) of the amendment allowed postenactment devices to be placed on the market without securing FDA approval so long as they were substantially equivalent to the preenactment device.⁸⁴ This pass to the market was not, however, meant to be a complete immunity to regulation, but rather it was a measure to level the playing field until FDA promulgated a regulation triggering the approval requirement for the specific type of device.⁸⁵

This concept of substantial equivalence in FDA regulation was not actually meant to be a substitute for determining the safety of new devices, but rather as a compromise for allowing the continued promotion of innovation in the medical device industry while the limited resources and personnel of the FDA could figure out what regulations were necessary for each type. What’s more troubling than the idea of using the test as a substitute for safety, however, was that what “substantial equivalence” meant for FDA approval was

⁸³HUTT & MERRILL, *supra* note 17, at 753.

⁸⁴*Id.*

⁸⁵*Id.*

initially left rather ambiguous in the statute.⁸⁶ The only controlling commentary from which the definition could be derived was that:

The term substantially equivalent is not intended to be so narrow as to refer only to devices that are identical to marketed devices nor so broad as to refer to devices which are intended to be used for the same purposes as marketed products. The Committee believes that the term should be construed narrowly where necessary to assure the safety and effectiveness of a device but not so narrowly where differences between a new device and a marketed device do not relate to safety and effectiveness. Thus, differences between new and marketed devices in materials, design or energy source, for example, would have a bearing on the adequacy of information as to a new device's safety and effectiveness, and such devices should be automatically classified into class III. On the other hand, copies of devices marketed prior to enactment, or devices whose variations are immaterial to safety and effectiveness would not necessarily fall under the automatic classification scheme.⁸⁷

The ambiguity of substantial equivalence continued for a considerable amount of time, while more devices were let into the market by claiming a link to post enactment devices. Eventually, the FDA made a clearer statement as to what it believed substantial equivalence had meant.⁸⁸ The use of the substantial equivalence test was later further broadened to allow not only linking new medical devices to ones created before the enactment, but also to medical devices that were created postenactment but could themselves claim substantial equivalence to a preenactment device. This “piggy backing” effect was meant to allow for the continued innovation of devices in fear that not allowing the link would once again hinder the market from expanding beyond 1976 technologies.⁸⁹

While it is not really clear that comparing technologies as a substitute for safety sought by the FDA is truly effective, this scheme has the added problem that it has the potential of placing inventors in a difficult position with respect to patent law. If the inventor of a postenactment device attempts to attain a patent on his invention, he is left in a position of claiming something as new to one agency while claiming its substantial

⁸⁶Id. at 754.

⁸⁸Goldberger, *supra* note 3, at 323.

⁸⁹Id. at 325.

equivalence to an old device to another agency. What makes this situation even more troubling is that the phrase “substantial equivalence” is not foreign to the realm of patent law. It is, in fact, a key element to a very important aspect of patent litigation – the Doctrine of Equivalence.

A. The Doctrine of Equivalence

Once a patent is granted, the patentee has the right to enforce its exclusivity on anyone considered an infringer.⁹⁰ An infringer is anyone who without authority of the patent holder makes, uses, or sells the patented invention within the U.S. during the term of the patent.⁹¹ In an infringement suit, the patent holder must prove that one or more of the claims within the patent are being infringed by the alleged infringer by proving that the claims literally read onto the allegedly infringing product, or through the doctrine of equivalents are substantially equivalent to the patent.

It is important to note that the concept of infringement on its own is not problematic in the case of someone seeking a new patent once an old patent expires. To gain a patent, however, it must be proven that the invention is new,⁹² useful,⁹³ and not obvious from the current art.⁹⁴ A patent therefore may be anticipated if all that it claims exists in a preexisting invention. The concept of anticipation is often defined in terms of infringement; namely that “anticipation and infringement are reciprocals, i.e., it is an elemental principle of patent law that a structure in a prior art reference which would infringe the patent if later in time, anticipates it if earlier in time.”⁹⁵ It is therefore necessary to ask whether through the Doctrine of Equivalents a

⁹⁰See 35 U.S.C. § 281.

⁹¹See 35 U.S.C. § 271.

⁹²See 35 U.S.C. § 101.

⁹³*Id.*

⁹⁴See 35 U.S.C. § 103.

⁹⁵*John Gladstone Mills, Donald C. Reiley, Robert Highley, Patent Law Basics* § 7:6 (citing *Knapp v. Morss*, 150 U.S. 221, 228, 14 S. Ct. 81, 37 L. Ed. 1059 (1893); *Procter & Gamble Co. v. Nabisco Brands, Inc.*, 711 F. Supp. 759, 768, 11 U.S.P.Q.2d

preexisting device anticipates that which the inventor is trying to claim. As will be discussed later, this issue is less important given the current case law, but it was highly relevant at the time the substantial equivalence test was created for the FDA.

Similarly to the somewhat ambiguous definition of substantial equivalence used by the FDA, the concept of equivalency in patent law is also slightly unpredictable. The Doctrine initially originated more than a hundred and fifty years ago in *Winans v. Denmead*.⁹⁶ The basic concept in determining equivalency was best described by the United States Supreme Court as:

What constitutes equivalency must be determined against the context of the patent, the prior art, and the particular circumstances of the case. Equivalence, in the patent law, is not the prisoner of a formula and is not an absolute to be considered in a vacuum. It does not require complete identity for every purpose and in every respect. In determining equivalents, things equal to the same thing may not be equal to each other and, by the same token, things for most purposes different may sometimes be equivalents. Consideration must be given to the purpose for which an ingredient is used in a patent, the qualities it has when combined with the other ingredients, and the function which it is intended to perform. An important factor is whether persons reasonably skilled in the art would have known of the interchangeability of an ingredient not contained in the patent with one that was.⁹⁷

Perhaps more relevant in this particular situation, the Doctrine is at times interpreted to mean that one device infringes another if it works in substantially the same way and accomplishes substantially the same result.⁹⁸

As stated earlier, in order to avoid the delay on return of investments, most companies and inventors of medical devices would want to use the substantial equivalence exception (often called the 510(k) exception

(BNA) 1241, 1248 (D. Del. 1989)).

⁹⁶15 How. 330, 56 U.S. 330 (1853).

⁹⁸See e.g. *Union Paper-Bag Mach. Co. v. Murphy* 97 U.S. 120, 125 (1877).

after its location in the amendment) to allow their invention to pass quickly through the premarket approval process by claiming it as a substantial equivalent to a preexisting device. The problem, however, is that at the same time these companies want to place their product on the market, and fully reaping the rewards of their research requires the companies and inventors to seek the exclusive right to practice their invention by obtaining a patent on their device. Stating to the FDA that the device is a substantial equivalent to a previous invention would then be a conflict of interest in seeking the protections a patent can provide.

B. Anticipation

As part of the patent application process, an oath is taken that the device which is the subject of the patent is new, useful and non-obvious.⁹⁹ For a device to meet the qualification of being new, however, it cannot be anticipated by a preexisting device. The patent applicant is therefore forced at the outset of seeking a patent to say that there is no device that anticipates the new invention. Very shortly after Section 510(k) was added, at least some practitioners noticed the inconsistency created for those required to take this oath and those seeking premarket approval of their devices.¹⁰⁰ Having the Doctrine of Equivalents well established by the time this section was added to the premarket approval process, it should have seemed clear to all that there may be a problem for someone to be able to both comply with the requirements of the PTO and benefit from the measures taken by the FDA to promote a fair market balance. Despite the issue's obviousness, there is no comment in the legislation of the 1976 amendments addressing whether it was even considered.

⁹⁹See 37 CFR §1.63.

¹⁰⁰Harry W. Barron, Irving S. Rappaport and Bruce A. Johnson, Medical Device and Patent Laws Clash?, 34 Food Drug Cosmo L.J. 304 (1979).

Although Congress may not have noticed the issue, the new FDA regulation to practitioners, posed the question of whether or not there was a need for the person seeking a patent to not only take the oath, but also to actually inform the PTO that a 510(k) notification was being filed with the FDA.¹⁰¹ Generally, a person only needs to inform the PTO of prior art that was either relied upon in the creation of the invention, or is at least relevant enough to bring into question what exactly is the applicant's invention in the face of what is already known. A notification to another agency would not really fall into the concept of prior art that the PTO expects to receive from an applicant.¹⁰² There is no question, however, that the disclosure to the FDA of substantial equivalence to a preexisting device would have been an extremely relevant piece of information for any PTO examiner to have when reviewing the application. It is not clear that even merely listing a device as prior art to the PTO is sufficient if an even greater claim of equivalence is being made to another agency.¹⁰³ It is very likely that there would be situations where representing a substantial equivalency claim to the FDA would require a technical discussion that would certainly assist the PTO in processing a patent application.¹⁰⁴ The more relevant the discussion with the FDA becomes, the more likely that the general duty of candor owed to the PTO would require disclosure of the 510(k) notification to the patent examiner,¹⁰⁵ and thereby hinder the chance of someone to attain a patent.

Although there may have been a duty to let the PTO know about the FDA interaction, that duty would end when the patent was issued. As stated earlier, the jurisdiction of the PTO lies only in the application for a patent - once issued it is beyond the PTO's control. An inventor might then hold off filing a Section

¹⁰¹Id at 314.

¹⁰²Id.

¹⁰³See Id.

¹⁰⁴See Id.

¹⁰⁵Id.

510(k) notification until the patent is granted.¹⁰⁶ The medical device which will be used for substantial equivalence, however, would undoubtedly be one that existed for the entire patent application. The duty of candor would not require the applicant to highlight that device to the patent examiner, however, because no weight was given to its existences when the application was filed.¹⁰⁷ The situation could even be that the medical device might not have to be cited as prior art to the patent examiner, and therefore would not exist as a factor in deciding whether to issue a patent at all.

In theory, it may very well be that at the time of the patent application, the old medical device did not seem relevant to the improvements claimed in the patent application. Should the patent ever come to be questioned in litigation, however, the fact that a substantial equivalence claim was eventually made to the FDA could still lead to a finding of inequitable conduct or fraud.¹⁰⁸ An inventor's ability to recuperate the costs of developing the invention may then be lost because of the confusion created by trying to satisfy two separate regulatory schemes.

One of the earliest solutions devised to help those facing the dilemma was to simply modify the representation made to the FDA with a single disclaimer.¹⁰⁹ The suggestion was to state that the medical device was a substantial equivalent, but to stress that the definition of substantial equivalence is not one that would cover patent law.¹¹⁰ On its face, the solution would likely work because it focused on the differences the two regulatory schemes are seeking to serve. It is not clear, that the solution does in fact eliminate the idea of

¹⁰⁶Id.

¹⁰⁷Id.

¹⁰⁸Id.

¹⁰⁹Id. at 318.

¹¹⁰The paper suggested footnoting the words "substantially equivalent" with the disclaimer: "The term 'substantially equivalent' as used herein is intended to be a determination of substantial equivalency under the Federal Food, Drug, and Cosmetic Act and relates to the fact that the product can be marketed without pre-market approval or reclassification. Such a determination is not intended to have any bearing whatsoever on the resolution of patent infringement suits or other patent matters." Id.

fraud or inequitable conduct with the PTO though, because disclosure to the PTO is not a necessary aspect of the process. The fact that Congress has not tried to resolve the conflict of regulations, however, may mean that at least some law makers saw the solution as adequate.

Although there does not appear to be any legislation directed at resolving the dual regulation dilemma, inventors do have some ways of complying with both requirements. The simplest way to allow a link between two inventions to exist is if both inventions are controlled by the same person. A second patent, known as a continuation patent, can be granted to inventor even though it is extremely close to the first patent claimed.¹¹¹ Substantial equivalence between these two patents would be acceptable because the first patent cannot count against the second. There is, however, a limitation on the ability to use a continuation patent as a means to avoid the conflict faced by the inventor. Continuation patents have to be filed during the application process of the patent they continue.¹¹² The protection granted by the patents therefore overlaps for the majority of their terms. This solution, while allowing for complete confidence in adhering to both regulations, does not offer that great of an advantage to the creator of the medical device in terms of recouping costs of development.

If the inventor of the new medical device wants to introduce the invention after the old device's term has expired, the inventor requires an alternate way to adhere to both agencies' requirements. One possible solution is the definition that congress eventually added to the concept of substantial equivalence from the FDA's perspective. The definition of substantial equivalence to a preexisting device, rather than implying

¹¹¹See 37 CFR §1.53.

¹¹²Id.

identical technology, can now alternatively be defined as a device that:

(I) has different technological characteristics and the information submitted that the device is substantially equivalent to the predicate device contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that the device is as safe and effective as a legally marketed device, and

(II) does not raise different questions of safety and efficacy than the predicate device.¹¹³

An inventor can then claim that the device is in fact new in the technology it uses, but equivalent in that it does not raise concerns for safety not present in the old device. This is perhaps the simplest solution for a company or inventor concerned with avoiding any complications with the patent office. Rather than try to claim that the technology is simultaneously different and yet equivalent, the focus of the conversation with the FDA can remain on safety. In some sense, this is probably the most ideal of solutions because it links the FDA's substantial equivalence test back to the very problem it was addressing. It is not invention that drives the FDA regulation but safety, and proving that the new medical device is still safe is all that the FDA really needs to know. As with any possible solution, however, there is a drawback to relying on the alternate definition. Because the use of new technologies requires increased clinical testing, there is an increased cost of both time and money necessary for the medical device to be placed on the market. Obviously the cost would still be lower than having no ability to claim a substantial equivalence, but the greater cost may prohibit some companies from being able to use this solution.

A far cheaper solution possible to some facing the dilemma lies in the definition of the particular invention, rather than the definition of substantial equivalence. Not all patents issued encompass an entirely new device; some can be for a particular improvement for a device that already exists.¹¹⁴ If the claimed invention is merely an improvement to a preexisting medical device it would make sense for the inventor to claim that the

¹¹⁴See 35 U.S.C. § 101 (1952).

total device encompassing the invention is still a substantial equivalent to the medical device already on the market. It seems likely that as the general level of technology evolves, some of it would be able to enhance medical devices already in use, such as improved materials or algorithms for medical imaging devices. In that instance, the PTO would be rewarding the inventor for seeing the improvement new technologies can make, while still allowing the FDA to make sure that the devices remain safe for the population. By its very nature, however, this solution can only help a subset of those seeking to meet both regulatory requirements. Inventors who are claiming an entirely new device to the PTO cannot in any way use this method as a means to comply with the requirements of the two agencies.

One final option in justifying stating seemingly conflicting statements to the two agencies is to rely on the limit in which the doctrine of equivalents can be applied. Although Congress did not seem to address the fact that there may be two conflicting definitions, the judicial branch may have inadvertently solved the dilemma. As stated earlier, the doctrine's origin lies in the courts trying to refine the definition of infringement. It's fitting then that a solution applicable to many situations to solve the problem faced by those trying to comply with the FDA and PTO would also come from the judicial system. While the test of equivalents has been applied to see whether an invention is anticipated, the rule has developed certain limitations. Although at the time the FDA initially brought its use of the substantial equivalence there was a question of how the doctrine of equivalents would interact, case law has since diminished the role it can play. While the Supreme Court developed the concept of anticipation to encompass a parallel test for each one existing in infringement inquiries, the Federal Circuit had determined at the end of the 1980's that the doctrine of equivalents was outside the scope of an anticipation claim.¹¹⁵ More recent inventors therefore have a better assurance as to what they may try to claim when dealing with both of the agencies.

¹¹⁵Lewmar Marine, Inc. v. Barient, Inc. 827 F.2d 744, 748 (C.A.Fed., 1987) ("All infringements of a device do not anticipate in this sense. Some may be infringements under the doctrine of equivalents which, if one wished to draw a parallel, is somewhat akin to obviousness.").

Although the doctrine was removed from anticipation for reasons completely unrelated to this dual agency regulation dilemma, the fact is that it makes it simpler for companies and inventors to claim a substantial equivalence to the FDA and still be able to swear that the invention is in fact new. As will be discussed in the section to follow, however, even though anticipation may not encompass the Doctrine of Equivalents, it still has the potential to bar the granting of a patent. Additionally, an inventor still has to be careful because although all the claims of his invention must lie in a single piece of prior art, some of the anticipation can come from what is inherent rather than what is literally explained in the prior art.¹¹⁶ A representation to the FDA may then be seen as an admission that because the two devices are substantially equivalent, the old device may inherently possess the new device.

C. Obviousness

As stated previously, for a patent to be granted, the invention has to be new, useful and nonobvious. Even if the person seeking both a patent and premarket approval is able to survive the idea that the invention is anticipated because of its substantial equivalence to a preexisting device, there is still a need to prove that the invention was not obvious. This test requires that a person of ordinary skill in the relevant art would not have thought it obvious to create the invention.¹¹⁷ The test in nonobvious inquiries is very ambiguous and fact specific so it is generally hard to predicate whether or not an examiner will find that the invention was in fact obvious. Usually, at least four factors are considered in determining whether something was obvious; namely, “(1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) any objective indicia of nonobviousness.”¹¹⁸ The

¹¹⁶See *id.*

¹¹⁷See e.g., *Application of Sporck* 49 C.C.P.A. 1039, 1043, 301 F.2d 686, 689 (Cust. & Pat.App. 1962).

¹¹⁸*ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 546 (C.A.Fed., 1998) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17-18, 86

fact that the inventor is also claiming substantial equivalence to the FDA may have a heavy influence on the obviousness test. As discussed earlier, the doctrine of equivalents may not exist in full form in the test for anticipation, but it may be that the missing component of the test is now in the obviousness test.¹¹⁹ A patent applicant can therefore never be sure that they can fully comply with the requirements set by the two separate agencies.

Although there is a great potential for either patents to be invalidated or applications to be denied, it seems that the issue is more theoretical than practical. A search of the current case law could not find an instance where a patent was invalidated or denied based on representation of substantial equivalence to the FDA. This lack of judicial opinions may indicate that the problem does not exist, but it can also indicate that companies faced with the dilemma don't want the courts to get involved. To force the issue to be discussed within the court system may in fact resolve the dilemma by forcing companies to choose either the patent or the pre-market approval. Companies may then be facing a type of prisoner's dilemma in that so long as they all don't push the issue, they can benefit by having both premarket approval and a patent some of the time. Once the issue is brought to bear, it may very well be that an explicit act of Congress would be necessary to allow the continued practice of adherence to the two regulatory schemes possible.

V. Conclusion

S.Ct. 684, 15 L.Ed.2d 545 (1966)).

¹¹⁹Lewmar Marine, Inc., 827 F.2d at 748.

There is no question that the goals of both the FDA and the PTO are beneficial to all of American society. The power granted to these agencies to pursue their respective task is very substantial, and has been extremely effective. The safety produced by FDA regulation allows everyone to be confident in the instruments they are subject to when seeking medical treatment. At the same time, the temporary monopolies the PTO can grant has created the needed incentive for better technologies to be discovered in the medical field. When the two interests of innovation and safety collide, however, there is a great potential for the public to suffer. This harm is not of course the intent of either agency, but rather an understandable consequence when two independent organizations are trying to control the same subject matter. While the simplest solution would be to put the products solely under the control of one agency, neither is well equipped to handle the aims sought by the other agency. The best solutions it seems are the ones that come through some assistance by either Congress or the courts, though they are at times slow and ambiguous. Overall though, time has shown that the dual regulation, while cumbersome and at times confusing, has not completely hindered either innovation or safety. As technology continues to develop, however, there is always the potential that this dual regulatory system will slow or even stop medical devices before reaching the public they are meant to help.